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Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857


Attention: Claudia Grillo

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,610,163. The application was filed on March 15, 2004, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571)272-7744 (telephone) or (571)273-7744 (facsimile).


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Michael P. Morris
Boehringer Ingelheim Corporation
PO Box 368
900 Ridgebury Road
Ridgefield CT 06877-0368

RE: Spiriva HandiHaler (tiotropium bromide monohydrate)
Docket No. 04E-0304